## Title 19 - DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30 - Division of Regulation and Licensure Chapter 40 - Comprehensive Emergency Medical Services Systems Regulations

## PROPOSED REGULATIONS

19 CSR 30-40.XXX Standards for Stroke Center Designation.

PURPOSE: This amendment

EDITOR'S NOTE: I-R, II-R or IV-R after a standard indicates a requirement for level I, II III, or IV stroke center respectively. I-IH, II-IH, III-IH after a standard indicates an in-house requirement for level I, II or III stroke center respectively.

I-IA, II-IA, or IV-IA indicates an immediately available requirement for level I, II, III or IV stroke center respectively. I-PA, III-PA, III-PA indicates a promptly available requirement for level I, II or III stroke center respectively.

PUBLISHER'S NOTE: The Secretary of State has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

- (1) General Standards for Stroke Center Designation.
- (A) The hospital board of directors, administration, medical staff and nursing staff shall demonstrate a commitment to quality stroke care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a stroke center; assure that all stroke patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human and physical resources as needed for the stroke program; and establish a priority admission for the stroke patient to the full services of the institution. (I-R, II-R, III-R IV-R) 3
- 1. Stroke centers shall meet national guidelines as established by national organizations including but not limited to the Joint Commission and the Brain Attack Coalition (I-R, II-R, III-R).
- (B) Stroke centers shall agree to accept all stroke victims appropriate for the level of care provided at the hospital, regardless of race, sex, creed or ability to pay. (I-R, II-R, IV-R)
- (C) The hospital shall demonstrate evidence of a stroke program with a Stroke Team that has appropriate experience to maintain skill and proficiency in the care of stroke patients. Such evidence shall include: meeting of continuing education unit (CEU) requirements by professional staff; documented regular attendance of core neurologists and representation from neurosurgeons, emergency medicine physicians and anesthesiologists at stroke program performance improvement and patient safety program meetings; documentation of continued experience as defined by the stroke Medical Director in management of sufficient numbers of stroke patients to maintain skill levels; and outcome data on quality of patient care as identified for study by Emergency Medical Services regions. Regular attendance shall be defined by each stroke service, but shall be not less than fifty percent (50%) of all meetings. The stroke medical director must ensure and document dissemination of information and findings from the peer review meetings to the non-core stroke team members on the stroke call roster. 1, 2, 5, 6, 7, 11.19.21
  - 1. The stroke team shall be available 24 hours per day and consist of, but not limited to:
    - a. Physician experienced in diagnosing and treating cerebrovascular disease

- b. Another health care professional, (i.e.) nurse, physician's assistant, nurse practitioner. (I-R/IA, II-R/IA III-R/IA IV-R/IA) **2, 6, 7**
- 2. The expanded multidisciplinary team shall include an appropriate representative from hospital administration, emergency medical services, emergency department, stroke ICU, pharmacy, CT/radiology, stroke unit, rehabilitation, discharge planning, nutritional services and laboratory. (I-R, II-R, III-R) 19, 23
- (D) There shall be a lighted designated helicopter landing area at the stroke center to accommodate incoming medical helicopters. (I-R, II-R, III-R IV-R)
- 1. The landing area shall serve solely as the receiving and take-off area for medical helicopters and shall be cordoned off at all times from the general public to assure its continual availability and safe operation. (I-R, II-R, III-R IV-R)
- 2. The landing area shall be on the hospital premises no more than three (3) minutes from the emergency room. (I-R, II-R, III-R IV-R)
- (E) The hospital shall appoint a board-certified physician, including, but not limited to three of the following:
  - Board certified neurologist or vascular neurosurgeon with a stroke fellowship, or neurocritical care fellowship, or vascular neurosurgery fellowship or equivalent experience
  - Board certified in vascular neurology or neurocritical care
  - Fellow of the Stroke Council of the AHA
  - Clinician who diagnoses and treats at least 50 patients with cerebrovascular disease annually or more than 50% of his/her time is dedicated to the care of cerebrovascular patients and/or research on cerebrovascular disease
  - Clinician with at least 10 peer-reviewed publications dealing with cerebrovascular disease
  - Clinician with at least 12 CME credits each year in areas directly related to cerebrovascular disease

to serve as the stroke medical director. (I-R, II-R, III-R) 5

- 1. There shall be a job description and organization chart depicting the relationship between the stroke medical director and other services. (I-R, II-R, III-R IV-R) 5
- 2. The stroke medical director shall be a member of the stroke team call roster. (I-R, II-R, III-R IV-R) **5, 7**
- 3. The stroke medical director shall be responsible for the oversight of the education and training of the medical and nursing staff in stroke care. (I-R, II-R, III-R IV-R) 5, 11
- 4. The stroke medical director shall document a minimum average of twelve (12) hours of continuing medical education (CME) in cerebrovascular disease every year. (I-R, II-R, III-R IV-R) **5, 11**
- 5. The stroke medical director shall participate in the stroke center's research and publication projects. (I-R) **5**, **18** 
  - **6.** The hospital shall appoint a physician to serve as the Stoke medical director. IV-R
- (F) There shall be a stroke program manager who is a registered nurse. (I-R, II-R, III-R IV-R) 16
- 1. There shall be a job description and organization chart depicting the relationship between the stroke program manager and other services. (I-R, II-R, III-R IV-R)
- 2. The stroke program manager shall document a minimum average of ten (10) hours of continuing nursing education in cerebrovascular disease every year and attend one national or regional meeting every other year that focuses on some aspect of cerebrovascular disease. (I-R, III-R, III-R, IV-R) 11, 16
- (G) All members of the stroke team call roster and emergency medicine physicians shall document a minimum average of eight (8) hours of CME in cerebrovascular disease every year. (I-R, II-R, IV-R) 7, 11
  - (H) There shall be a specific and well-organized system for rapidly notifying and activating the stroke team to evaluate patients presenting with symptoms suggestive of an acute stroke. (I-R, II-R, III-R IV-R) 2, 7

- (I) Level III or Level IV stroke centers shall have a call roster providing 24 hour a day backup neurology coverage or networking agreement with Level I or Level II stroke center for telephone consult or telemedicine when a neurologist is not available. The Level III or IV shall have an expedited transfer agreement with the Level I or Level II stroke center. 2, 4.8
  - (J) Rehabilitation services shall be directed by a physician with board certification in physical medicine and rehabilitation or by other properly trained individuals (i.e., neurologist experienced in stroke rehabilitation. (I-R, II-R) 17
  - (K) Consults for physical medicine and rehabilitation, physical therapy, occupational therapy, and speech therapy shall be requested and completed within 24 hours of admission. (I-R, II-R) 2, 17
  - (L) The hospital shall demonstrate that there is a plan for adequate post-discharge follow-up on stroke patients, including rehabilitation. (I-R, II-R, III-R) 17, 23
  - (M) Hospital shall keep stroke team log which contains the following: (I-R, II-R, III-R IV-R)
    - 1. Response times
    - 2. Patient diagnosis
    - 3. Treatment/actions
    - 4. Outcomes (I-R, II-R, III-R IV-R) 1, 7
  - (N) A Missouri stroke registry shall be completed on each stroke patient and meets the following criteria: Includes at least one (1) code within the range of the following diagnostic codes as defined in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9)-(CM) XXX-XXX which is incorporated by reference in this rule as published by the Centers for Disease Control and Prevention in 2006 and is available at National Center for Health Statistics, 1600 Clifton Road, Atlanta, Georgia 30333. This rule does not incorporate any subsequent amendments or additions and must include one of the following criteria: hospital admission, or patient transfer out of facility or death resulting from the stroke (independent of hospital admission or hospital transfer status.) The registry shall be submitted electronically in a format defined by the Department of Health and Senior Services. Electronic data shall be submitted quarterly, ninety (90) days after the quarter ends. The stroke registry must be current and complete. A patient log with admission date, patient name, and diagnosis must be available for use during the site review process. Information provided by hospitals on the stroke registry shall be subject to the same confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R IV-R) 1
- (O) The hospital shall have a one-call stroke team activation protocol that establishes the criteria used to rank stroke patients according to time of symptom onset and identifies the persons authorized to notify stroke team members when a suspected stroke patient is en route or has arrived at the stroke center. (I-R, II-R, III-R IV-R) 7, 10
- 1. The one-call stroke team activation protocol shall provide for immediate notification and response requirements for stroke team members when a suspected stroke patient is en route to the stroke center. (I-R, II-R, III-R IV-R) 2, 7, 10
- (P) The hospital shall have a plan to notify an organ or tissue procurement organization and cooperate in the procurement of anatomical gifts in accordance with the provisions in section 194.233, RSMo. (I-R, II-R, III-R IV-R)
- (Q) There shall be no level III or IV stroke centers designated within fifteen (15) miles of any Missouri level I or II stroke center.
- (2) Hospital Organization Standards for Stroke Center Designation.
- (A) There shall be a delineation of privileges for the neurologists/neurosurgeons made by the medical staff credentialing committee. (I-R, II-R, III-R) 6, 11
- (B) All members of the stroke team call roster shall comply with the availability and response requirements per the hospital protocol. If not on the hospital premises, stroke team members who are immediately available shall carry electronic communication devices at all times to permit

contact by the hospital and shall respond immediately to a contact by the hospital. (I-R, II-R, III-R, IV-R) 2, 7, 10

- (C)Physicians who are board-certified, or board-admissible and who are credentialed by the hospital for stroke care shall be on the stroke center staff and be available as indicated.
- 1. Neurology—I-R/IA, II-R/IA, III-R/PA 6, 11
  - A. The neurology staffing requirement may be fulfilled by a senior neurology resident credentialed in neurology. **6**, **11**
  - B. The neurologist shall be immediately available and in attendance with the patient when a neurology resident is fulfilling availability requirements. **2**, **6**
- 2. Neurologic surgery—I-R/IA, II-R/IA 2, 6
  - A. The neurologic surgery staffing requirement may be fulfilled by a surgeon who has been approved by the chief of neurosurgery for care of stroke patients. **6**, **11**
  - B. The surgeon shall be capable of initiating measures toward stabilizing the patient and performing diagnostic procedures. 6
  - C. In a level I or II stroke center call rosters providing back-up neurosurgeon coverage will be maintained. 6
- 3. Emergency medicine—I-R/IH, II-R/IH, III-R/IH IV-R/IA 2, 13
- 4. Neuro Endovascular specialist—I-R/IA 6
- 5. Diagnostic Radiology—I-R/PA, II-R/PA, III-R/PA 2, 12
- 6. Anesthesiology—I-IH, II-R
  - A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents or certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in stroke patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents, anesthesia assistants or CRNA's are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is en route under the direction of the neurosurgeon, including induction of anesthesia.
- (3) Standards for Special Facilities/Resources/Capabilities for Stroke Center Designation.
- (A) The hospital shall meet emergency department standards for stroke center designation.
- 1. The emergency department staffing shall ensure immediate and appropriate care of the stroke patient. (I-R, II-R, III-R IV-R) 13
- A. The physician director of the emergency department shall be board-certified or board-admissible in emergency medicine. (I-R, II-R) **6,11,13**
- B. There shall be a physician trained in stroke care current in cerebrovascular CME in the emergency department twenty-four (24) hours a day (I-R, II-R, III-R) 2, 6, 11, 13
- C. There shall be written protocols defining the relationship of the emergency department physicians to other physician members of the stroke team. (I-R, II-R, IV-R) 7, 10, 13
  - D. All registered nurses assigned to the emergency department shall be credentialed in stroke nursing by the hospital within one (1) year of assignment. (I-R, II-R, III-R IV-R) 11, 13
  - E. Registered nurses shall document a minimum of eight (8) hours of stroke-related continuing nursing education per year. (I-R, II-R, III-R IV-R) 11, 13
  - F. The emergency department shall have written care protocols for triage and treatment of acute stroke patients available to ED personnel and should be reviewed and revised annually. (I-R, II-R, III-R, IV-R) **2**, **10**, **13**
- 2. Equipment for resuscitation and life support with age appropriate sizes shall include the following:
- A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, sources of oxygen and mechanical ventilator I-R, II-R, III-R, IV-R (except mechanical ventilator):

- B. Suction devices I-R, II-R, III-R IV-R;
- C. Electrocardiograph, cardiac monitor and defibrillator I-R, II-R, III-R, IV-R;
- D. Central line insertion equipment-I-R, II-R, III-R, IV-R;
- E. All standard intravenous fluids and administration devices including intravenous catheters and IO. I-R, II-R, III-R IV-R;
- F. Sterile surgical sets for procedures standard for the emergency department -I-R, II-R, III-R;
  - G. Gastric lavage equipment -I-R, II-R, III-R IV-R;
  - H. Drugs and supplies necessary for emergency care I-R, II-R, III-R, IV-R;
- I. Two-way radio linked with emergency medical service (EMS) vehicles-I-R, II-R, III-R, IV-R;
  - J. End-tidal carbon dioxide monitor--I-R, II-R, III-R, IV-R
- K. Temperature control devices for patient, parenteral fluids and blood-I-R, II-R, III-R IV-R;
  - L. Rapid infusion system for parenteral infusion-I-R, II-R, III-R, IV-R.
- 3. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R, IV-R, IV-R)
- 4. There shall be CT capability with twenty-four (24) hour coverage by technicians. (I-IH, II-IA) 2, 9, 12
- (B) The hospital shall have a designated stroke ICU for stroke center designation. (I-R. II-R) 15
  - 1. There shall be a designated stroke medical director for the ICU. (I-R, II-R) 5, 15
  - 2. A physician who is not the emergency department physician shall be on duty in the ICU or available in-house twenty-four (24) hours a day in a level I stroke center. 2, 6, 15
  - 3. The minimum registered nurse/patient ratio used shall be one to one (1:1) or one to two (1:2). (I-R, II-R)
  - 4. Registered nurses shall have a minimum of ten (10) hours of stroke-related continuing nursing education per year. (I-R, II-R) 11, 15
  - 5. There shall be beds for stroke patients or comparable level of care provided until space is available in ICU. (I-R, II-R)
  - 6. Equipment for resuscitation and to provide life support for the stroke patient shall be available for the intensive care unit. This equipment shall include, but not be limited to:
    - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator (I-R, II-R)
    - B. Oxygen source with concentration controls-(I-R, II-R)
    - C. Cardiac emergency cart, including medications (I-R, II-R)
    - D. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R)
    - E. Electronic pressure monitoring and pulse oximetry (I-R, II-R)
    - F. End-tidal carbon dioxide monitor and mechanical ventilators (I-R, II-R)
    - G. Patient weighing devices (I-R, II-R)
    - H. Drugs, intravenous fluids and supplies (I-R, II-R)
    - I. Intracranial pressure monitoring devices (I-R, II-R)
  - 7. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R)
  - (C) The hospital shall meet post-anesthesia recovery room (PAR) standards for stroke center designation. (I-R, II-R)
- 1. Registered nurses and other essential personnel who are not on duty shall be on call and available within **sixty (60)** minutes. (I-R, II-R)
- 2. Equipment for resuscitation and to provide life support for the stroke patient shall include, but not be limited to:
  - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen and mechanical ventilator-(I-R, II-R)
  - B. Suction devices (I-R, II-R)
  - C. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R)

- D. All standard intravenous fluids and administration devices, including intravenous catheters (I-R, II-R)
- E. Drugs and supplies necessary for emergency care (I-R, II-R)
- (D) The hospital shall have stroke rehabilitation or a written transfer agreement. (I-R, II-R, III-R, IV-R)
- (E) Radiological capabilities for stroke center designation including a mechanism for timely interpretation to aid in patient management shall include: 2, 9, 12
- 1. Angiography with interventional capability available twenty-four (24) hours a day with a 1 (one) hour maximum response time (I-R, II-R)
  - 2. Resuscitation equipment available to the radiology department-I-R, II-R, III-R;
  - 3. In-house computerized tomography (I-R, II-R, III-R) 9, 12
  - 4. Computerized tomography technician (I-IH, II-IH, III-IA) 2, 9, 12
- (F) There shall be documentation of adequate support services in assisting the patient's family from the time of entry into the facility to the time of discharge. (I-R, II-R, III-R) 23
- (G) The stroke unit of a designated stroke center shall have the following personnel and equipment: (I-R, II-R, III-R) **14**
- 1. Registered nurses and other essential personnel on duty twenty-four (24) hours a day (I-R, II-R) 2, 14
- 2. Equipment for resuscitation and to provide support for the stroke patient including, but not limited to:
  - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator and sources of oxygen (I-R, II-R, III-R)
  - B. Suction devices (I-R, II-R, III-R)
  - C. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R, III-R)
  - All standard intravenous fluids and administration devices and intravenous catheters (I-R, II-R, III-R)
  - E. Drugs and supplies necessary for emergency care (I-R, II-R, III-R)
- 3. Documentation that all equipment is checked according to the hospital preventive maintenance schedule (I-R, II-R)
- (H) The operating room personnel, equipment and procedures of a stroke center shall include, but not be limited to:
  - 1. An operating room adequately staffed in-house twenty-four (24) hours a day (I-R, II-R)
  - 2. Equipment including, but not limited to:
    - **A**. Operating microscope-(I-R, II-R);
    - B. Thermal control equipment for patient, parenteral fluids and blood (I-R, II-R)
    - C. X-ray capability- (I-R, II-R)
    - D. Instruments necessary to perform an open craniotomy-(I-R, II-R)
    - E. Monitoring equipment-(I-R, II-R)
  - 3. Documentation that all equipment is checked according to the hospital preventive maintenance schedule-I-R, II-R, III-R;
- (I) The following clinical laboratory services shall be available twenty-four (24) hours a day: 2,
  - 1. Standard analyses of blood, urine and other body fluids-(I-R, II-R, III-R, IV-R) 24
  - 2. Blood typing and cross-matching—(I-R, II-R, III-R) 24
  - 3. Coagulation studies—(I-R, II-R, III-R, IV-R) 24
  - 4. Comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities- (I-R, II-R, III-R) 24
  - 5. Blood gases and pH determinations- (I-R, II-R, III-R, IV-R) 24
  - 6. Blood chemistries (I-R, II-R, III-R, IV-R) 24

(4) Standards for Programs in Performance Improvement Patient Safety Program, Outreach, Public Education and Training for Stroke Center Designation.

- (A)There shall be an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review and evaluate the quality, timeliness and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems. (I-R, II-R, III-R IV-R) 1, 2, 21
- (B) The following additional performance improvement and patient safety measures shall be required:
  - 1. All stroke centers shall collect, trend and electronically report to the Department key data indicators as identified by Department of Health and Senior Services. (I-R, II-R, III-R, IV-R) 1, 21
  - 2. Regular reviews of all stroke-related deaths—(I-R, II-R, III-R, IV-R) 1, 21
  - 3. A regular morbidity and mortality review, at least quarterly-(I-R, II-R, III-R, IV-R) 1, 21
  - 4. A regular multidisciplinary stroke meeting that includes representation of all members of the stroke team, with minutes of the meetings to include attendance, adherence to the stroke protocol and findings-I-R, II-R, IV-R; 1, 7, 10, 19, 21
- 5. Regular reviews of the reports generated by the Department of Health and Senior Services from the Missouri stroke registry (I-R, II-R, IV-R) 1, 21
- 6. Regular reviews of pre-hospital stroke care including inter-facility transfers (I-R, II-R, III-R, IV-R) 1, 21
  - 7. Participation in EMS regional systems of stroke care as established by the Department of Health and Senior Services (I-R, II-R, IV-R)
- 8. Stroke patients remaining greater than six (6) hours prior to transfer will be reviewed as a part of the performance improvement and patient safety program. I-R, II-R, III-R, IV-R. 1, 2, 21
- (C) A neurology outreach program shall be established to assure twenty-four (24) hour availability of telephone consultation or telemedicine with physicians in the outlying region. (I-R, II-R) 2, 6, 8
- (D) A <u>public education</u> program shall be established to promote stroke prevention and signs and symptoms awareness and to resolve problems confronting the public, medical profession and hospitals regarding optimal care. (I-R, II-R,III-R) **20**
- (E) The hospital shall be actively involved in local and regional EMS systems by providing training and clinical resources. (I-R, II-R)
- (F) There shall be a hospital-approved procedure for credentialing nurses in stroke care. (I-R, II-R, IV-R) 11
- 1. All nurses providing care to stroke patients and assigned to the emergency department or ICU shall complete a minimum of sixteen (16) hours of stroke nursing courses to become credentialed in stroke care. (I-R, II-R, IV-R) 2, 11, 15
- 2. The content and format of any stroke nursing courses developed and offered by a hospital shall be developed in cooperation with the stroke medical director. A copy of the course curriculum used shall be filed with the HSL. (I-R, II-R, IV-R)
- (G) A hospital diversion protocol must be maintained in accordance with state regulations. This protocol is designed to allow best resource management within a given area. This protocol must contain a defined performance improvement and patient safety process to review and validate established criteria within that institution. Hospital diversion information must be maintained to include date, length of time and reason for diversion.
- (5) Standards for the Programs in Stroke Research for Stroke Center Designation.
- (A) The hospital and its staff shall support a research program in stroke as evidenced by any of the following: 3, 18
  - 1. Publications in peer reviewed journals--I-R; 18
  - 2. Reports of findings presented at regional or national meetings--I-R; 18
  - 3. Receipt of grants for study of stroke care--I-R; and 18
  - 4. Production of evidence based reviews--I-R. 18

(B) The hospital shall agree to cooperate and participate with the DHSS in conducting epidemiological studies and individual case studies for the purpose of developing stroke prevention programs. (I-R, II-R, III-R, IV-R) 3,18

## **AUTHORITY**

\*Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987 amended 1998.

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions

PRIVATE COST: This proposed amendment will cost private entities

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Kimberly O'Brien, Director, Department of Health and Senior Services, Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.